

**§ 890.5150 Powered patient transport.**

(a) *Identification.* A powered patient transport is a motorized device intended for medical purposes to assist transfers of patients to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs. This generic type of device does not include motorized threewheeled vehicles or wheelchairs.

(b) *Classification.* Class II (performance standards).

**§ 890.5160 Air-fluidized bed.**

(a) *Identification.* An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(b) *Classification.* Class II (performance standards).

**§ 890.5170 Powered flotation therapy bed.**

(a) *Identification.* A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(b) *Classification.* Class II (performance standards).

**§ 890.5180 Manual patient rotation bed.**

(a) *Identification.* A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.

(b) *Classification.* Class I (general controls).

**§ 890.5225 Powered patient rotation bed.**

(a) *Identification.* A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to

treat severe and extensive burns, urinary tract blockage, and to aid circulation.

(b) *Classification.* Class II (performance standards).

**§ 890.5250 Moist steam cabinet.**

(a) *Identification.* A moist steam cabinet is a device intended for medical purposes that delivers a flow of heated, moisturized air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.

(b) *Classification.* Class II (performance standards).

**§ 890.5275 Microwave diathermy.**

(a) *Microwave diathermy for use in applying therapeutic deep heat for selected medical conditions—*(1) *Identification.* A

microwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Microwave diathermy for all other uses—*(1) *Identification.* A microwave diathermy for all other uses except for

the treatment of malignancies is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

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